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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,473	01/29/2001	Michel Philippe	05725.0834	6832

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,473

Applicant(s)

PHILIPPE ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 31-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-59 are pending in the present application. Claims 31-59 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-30 stand rejected as indicated below.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-30 under 35 USC 112, first paragraph is maintained.

Applicant argues that under MPEP § 2164.01(b), as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 USC § 112 is satisfied. According to applicant, a genus is typically identifiable based on common attributes and, thus, testing a species within that genus can demonstrate a reasonable correlation to the entire scope of the claims. Thus, it is applicant's argument that the present specification provides for numerous examples that bear a reasonable correlation to the entire scope of the instant claims. Applicant's argument was considered but not persuasive for the following reason.

The instant claims encompass the utilization of the claimed compounds for treatment of any disorder associated “with seborrhea” or “with microorganisms of the genus *Propionibacterium*”. Applicant’s argument that a genus is typically identifiable based on common attributes and, thus, testing a species within that genus can demonstrate a reasonable correlation to the scope of the claims is noted but not persuasive for the mere fact that the various species of the genus *Propionibacterium* do not all cause acne. For example, the species “*Propionibacterium acne*” disclosed by the present disclosure is commonly found in acne pustule; however, the species “*Propionibacterium propionicus*” causes lacrimal canaliculitis and actinomycosis (see Stedman’s Medical Dictionary 27th Edition). There are also some species of the genus *Propionibacterium* that are known to produce a protein that inhibits the growth of those species that cause acne, for example *Propionibacterium jensenii* (see for example, US 5,981,473, col. 1, lines 9-13, 41-53; col. 2, lines 26-41; col. 3, lines 41-50). Therefore, the showing of the effectiveness of the claimed compounds against two species, i.e., *Propionibacterium acne* and *Propionibacterium granulosum*, does not provide support for the utilization of said compounds for treating all “disorders associated with microorganisms of the genus *Propionibacterium*” because there is variation between the species of the genus *Propionibacterium*. Therefore, the examiner maintains that there is insufficient support in the present specification for the entire scope of the claimed invention.

For this reason and those given in previous Office Actions, the rejection of claims 1-30 under 35 USC 112, first paragraph is maintained.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1-10, 12-15, 25-27 and 30 under 35 USC 102(e) over Thunemann (US 6,395,284) as evidenced by Aldrich (1996-1997) is maintained.

Applicant argues the reference discloses mesomorphic complexes of vitamin A with cationic polyelectrolytes to assist in immobilization of vitamin A and does not disclose nor direct one to a particular cationic polyelectrolyte nor to the use of the polyelectrolyte as an active agent to treat acne. Applicant's argument was considered but not persuasive for the following reasons.

The claimed invention is to the use of agents **comprising** at least one polyamino acid derivative as defined by the instant claims. The reference teaches a composition comprising a polyamino acid derivative for use in treating acne (see especially Example 6). The instant claims encompass the prior art composition because it recites "comprising" which is inclusive of any composition containing the claimed polyamino acid derivatives for use in treatment of acne. The fact that the reference does not specifically teach the use of polyamino acids as the active agent is not persuasive because the skilled artisan would have the reasonable expectation that similar compositions would have similar properties.

Applicant also argues the reference does not disclose nor direct one to a particular cationic polyelectrolyte. The reference provides direction to the use of polyamino acids as polyelectrolytes by (a) the specific disclosure of poly-L-lysine retionate in example 6 and (b) the teaching that the use of polyamino acids would be

advantageous over other polyelectrolytes because they are readily biodegradable (see col. 9, lines 59-62).

For these reasons and those given in previous Office Actions, the rejection of claims 1-10, 12-15, 25-27 and 30 under 35 USC 102(e) over Thunemann (US 6,395,284) as evidenced by Aldrich (1996-1997) is maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB

June 6, 2005